REMARKS OF

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TO

NATIONAL WHOLESALE DRUGGIST ASSOCIATION

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There are nine months left in the Reagan Administration, and the pundits are already writing Ronald Reagan's legacy.

It will come as no surprise to you that my version of the Reagan health legacy is quite critical. I predict that in ten years people will look back and ask how so many health problems were ignored and unsolved during the Reagan years.

This Administration has a habit of trying to shift responsibility for health care to other levels of government, and denying that health care needs must be met.

- We have seen an explosion in the number of Americans with no form of health insurance. Their ranks now total 37 million and counting. Their plight is well documented. Their fate is ignored.

- The AIDS epidemic races ahead, jeopardizing the lives of millions in this country and abroad. This country's public hospitals are near the breaking point. Employers, schools, and average citizens desperately seek guidance. But the watchword of the Reagan Administration has been to go slow. Their idea of leadership is to trail far behind the recommendations of the Congress -- and the President's own commission on AIDS.

- Rising health care costs strain federal and state health budgets and employers' health benefits plans. The Administration's response is to talk about "competition". Their only action is to cut the federal share of the Medicaid program for the poor.

- By the year 2000, our rapidly aging population will present overwhelming new demands on our health care system that we are not prepared to meet. High ranking Administration officials startle audiences with frightening data about the future health care demands of graying baby boomers. No solutions or preparations are forthcoming.

The next President has a formidable job. The price of continuing to ignore these matters is too high.

Medicare Catastrophic Health Bill

To its credit, the administration did respond to the prodding of Congress and recognize a very important health care problem for the aged -- catastrophic health costs.

Secretary Bowen put catastrophic coverage under Medicare on the health agenda. But there were serious limitations in the Administration's approach. One of those was in the area of catastrophic drug costs. Along with long term care expenses, drug costs are one of the gaps in Medicare that our senior citizens are most anxious to have addressed.

Outpatient prescription drugs are not currently covered by Medicare, with the exception of immunosuppressive drugs needed by an organ transplant recipient. This imposes a substantial burden on enrollees.

The elderly use 30 percent of all prescription drugs in this country, and use them at roughly three times the rate of the non-elderly. Many have chronic conditions that require them to take expensive medications on a daily basis to remain active, or sometimes, alive.

The Medicare Catastrophic bills passed by the House and Senate represent the first major improvement in Medicare benefits since 1965. It is not a minute too soon. The Congressional

Budget Office estimates that over 6 million Medicare beneficiaries spend over $500 a year on prescription drugs. Their average annual cost for drugs is $1000.

The cost of adding this new drug coverage is significant, but it does not increase the Federal deficit. The benefit is funded totally by higher premiums on Medicare beneficiaries. Not a single dollar of general revenues will be used.

The House bill would cover, starting in 1989, all outpatient prescription drugs after a $500 deductible is met. Medicare would then pay for 80% of the cost of drugs. When generic substitutes are available, Medicare would pay at the generic rate unless the prescribing doctor handwrites on the prescription that the brand drug is medically necessary.

With Medicare paying for drugs and other catastrophic medical care costs for low-income Medicare beneficiaries who are also eligible for Medicaid, there will be reductions in state Medicaid programs expenditures. This allows us to improve Medicaid coverage for the poor. The House bill requires the states to pay the Medicaid premiums, deductibles amd coinsurance for elderly and disabled people below the poverty line.

The Senate bill phases in coverage very slowly. Only in 1993 would all drugs be covered.

Starting in 1990, the Senate bill would pay for chemotherapy, antibiotics taken intravenously, and immunosuppressive drugs. In 1991 and 1992, cardiovascular and diuretic drugs would be included. For all these, a $600 deductible would be required before Medicare would pay its 80% share. Generics would be required as in the House bill. Enrollees with incomes below poverty would not be protected to the same extent as in the House bill.

The Senate bill would provide substantially less help for needy Medicare enrollees. By 1992, the Senate would cover 2.4 million beneficiaries while the House would reach 6.2 million.

Both bills introduce the concept of "participating pharmacies". These pharmacies would sign an agreement not to charge Medicare patients more than the general public, to assist enrollees in determining whether their deductible had been met, to file information to that effect on behalf of the enrollee with Medicare, to accept assignment on all prescriptions after the deductible is met, and to counsel enrollees on generics and proper drug use.

Before the Senate voted on its bill, the brand name drug companies conducted a multi-million dollar national attack on the bill. They claimed in their extensive advertisements that they were only concerned about the high premiums for the elderly. The real reason for their opposition was their fear of Congressional

cost controls.

They now see that the bill will include a provision covering prescription drugs, so they support the Senate bill.

The Administration also has dropped its outright opposition and now supports the Senate drug benefit. It is certain that a drug benefit, with a generic preference, will be enacted.

Medicare Catastrophic Conference

The House and Senate are now meeting in conference. We are progressing slowly, and it may be several weeks before we finish.

The main issue dividing us is the Senate's insistence on a very slow phase-in of coverage. They argue that the cost estimate of the Congressional Budget Offices may be too low, and so we should move more slowly.

I do not share the Senate's fears about massive cost overruns; but I am concerned, as are other House conferees, that the Medicare premiums financing this new drug benefit not get too high.

Given the Senate's lack of confidence in the CBO estimate,

the House conferees have decided to agree to a phase-in, but one that is much shorter. The crucial question is how to do it. We will be facing this and a number of other contentious issues in the weeks to come.

Drug Prices

A major factor in Congress deciding to cover out-patient prescription drugs under Medicare is the very high price tags they carry. High prices make drugs inaccessible to the elderly.

We are in the midst of a new era of prescription drug marketing and pricing. It appears that brand name companies have decided that there are no limits to what they can charge.

They claim their price increases are justified by ever-increasing costs of research and development. At the July, 1985 hearing of my Subcommittee on Health and the Environment on drug price increases, the drug companies vigorously made just this argument.

I took them at their word and asked them for proof. In preparation for the second Subcommittee hearing on drug price increases in April of last year, I conducted a survey of the 25 largest research-based companies. Their combined drug sales

represented 2/3 of all sales.

Their data indicated that their prices had risen 3 times faster than necessary. For those companies, in 1982 to 1986, revenues from price increases were $4.7 billion. Revenues from volume increases and new drugs were another $4.2 billion. During that same time period, the total increase in R and D costs was only $1.6 billion.

Even when faced with these facts, the Pharmaceutical Manufacturers Association persists with the unfounded claims, and the companies with their price increases.

High drug prices deprive many Americans of essential therapy. The elderly are the hardest hit because they need so many drugs. With the new Medicare drug benefit Congress will not subsidize the multi-billion dollars profits of drug companies. If their price hikes persist, I am confident there will be prompt Congressional action.

Orphan Drug Amendments

With all the attention on the commonly used drugs and their costs, little note has been taken of another important program.

Five years ago, the Congress passed the Orphan Drug Act, incorporating into legislation the public's strong resolve to discover and develop drugs for rare diseases. At that time, we had high expectations and we talked of the enormous good the act would do.

Today, we can take great pride in the incredible success of the orphan drug program. In five years, development and testing of over 190 orphan drugs has taken place, and 24 orphan drugs have been approved. This represents over five times as many drugs under development since the Act as during the ten years prior to enactment.

Some amendments to the Orphan Drug Act were enacted in April. They will continue the orphan drug grant program, which makes grants to independent researchers when no private pharmaceutical company will sponsor the testing and development of an orphan drug. The grant program was also expanded to include orphan medical devices and orphan medical foods.

The Orphan Drug Act contains a number of incentives for the development of orphan drugs. Unquestionably, the most important is the seven-year exclusivity rule which provides an absolute monopoly. The FDA is prohibited from approving any other company for the same drug for the same rare disease, even if the second company is willing to do its own New Drug Application, complete with clinical trials.

This total ban on competition was intended to comfort potential sponsors. If they would undertake the development of drugs with little commerical value, Congress would guarantee them all the potential sales.

It is now clear that some companies are misusing the exclusivity provision. Instead of an incentive to develop drugs of little comerical value, the Act has become a shield for highly profitable drugs.

This issue came to a head with the recent approval of human growth hormone. Even though the patent population of 10,000 children is quite small, the annual price of more than $10,000 per child gives the drug significant commerical value.

The effect of the exclusivity rule is to block four other companies that want to market human growth hormone.

A commercially viable -- and highly profitable --drug can fit within a strict construction of the Orphan Drug Act. But the Congress never intended to extend the benefits of the Act to such drugs.

While I believe this unintended use of the Act must be stopped, there is considerable disagreement over how the Act should be changed. Because I did not want to jeopardize the reauthorization of the grant program, I did not include an

amendment in the bill just passed. Congress will return to this problem of market exclusivity in the next session.

Physician Dispensing

Let me mention one other issue I know is of concern to you.

In an editorial on March 28, 1987, under the heading "Doctors Shouldn't be Pharmacists," the New York Times posed some difficult questions:

> The physician/pharmacist has an obvious potential conflict of interest. Might he be tempted to write unnecessary prescriptions? Or to prescribe a drug he sells when another he doesn't sell might be preferable? Or to sell brand-name drugs with high markups when cheaper generics are available?

They asked the right questions. The answers go directly to the ethics of medical practice.

In our fee-for-service system, the immediate financial incentives favor performing additional medical services. But at least those services are principally medical ones, involving the skill and judgment of a physician.

When it comes to the act of selling a drug after a patient has been examined and a diagnosis and course of treatment has been decided on, however, the issue is different.

There are checks and balances in the current system. Professional licensed pharmacists provide a level of additional professional judgment. After leaving the doctor's office, patients can act as informed consumers in pharmacies, which are a marketplace for price competition.

The Subcommittee on Health and the Environment, which I chair, and the Committee on Energy and Commerce have passed legislation responding to these concerns.

The bill is H.R. 2168. It prohibits practitioners who are licensed to administer drugs from dispensing prescription drugs for their own profit, except in certain circumstances.

The prohibition does not apply to the dispensing of an oral drug or a vaccine, or in rural areas, or in an emergency or other situation when a patient would have substantial difficulty in obtaining drugs from a pharmacy.

These exceptions are necessary to balance patient's health care needs. With them, I believe the legislation is sound.

The bill is controversial. Its future is unclear. So far,

there has been no action in the Senate.

Conclusion

The 100th Congress has considered relatively few bills affecting the drug industry. If we are short on quantity, though, we have compensated with importance.

The Medicare Catastrophic legislation will have far-reaching effects on you and the brand and generic industries. The physician dispensing and orphan drug bills are carefully targeted on serious problems. I believe the Congress is hitting the bull's eye with each of these initiatives.